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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

STOCKTON, LAURA

ART UNIT PAPER NUMBER

1626

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,799

Applicant(s)

THORARENSEN ET AL.

Examiner

Laura L. Stockton, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 2-5, 7-26, 28-30 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 27 and 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/27/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

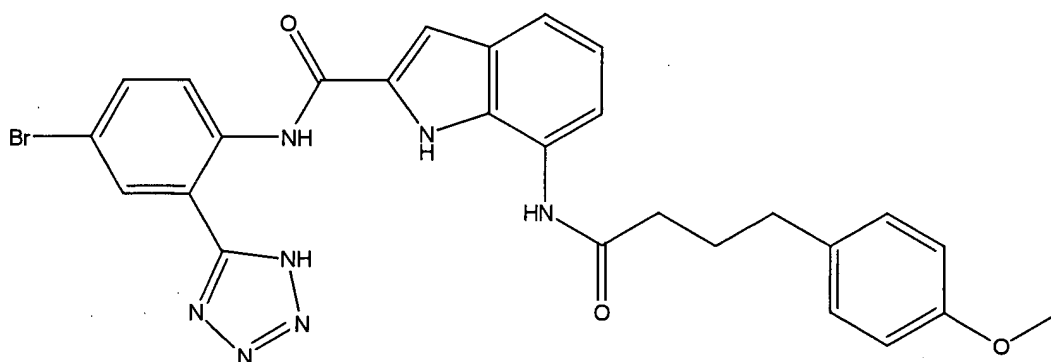
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DETAILED ACTION

Claims 1-37 are pending in the application.

Election/Restrictions

Applicants' election with traverse of Group IV, and the species N-[4-bromo-2-(1H-tetrazol-5-yl)phenyl]-7-{[4-(4-methoxyphenyl)butanoyl]amino}-1H-indole-2-carboxamide found on page 81, lines 13-14 of the instant specification (structure depicted below) in the reply filed on April 18, 2005 is acknowledged.



N-[4-bromo-2-(1H-tetrazol-5-yl)phenyl]-7-{[4-(4-methoxyphenyl)butanoyl]amino}-1H-indole-2-carboxamide

The traversal is on the ground(s) that: (1) the examination of all pending claims 1-37 of the present

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application is far less burdensome for both Applicants and the Patent Office than would be prosecution of 28 or more separately filed applications; (2) groups having common classifications (i.e., Gps I, IV, V, VI, VII, VIII, IX and XI) should be combined; and (3) under burden has not been alleged.

All of Applicants' arguments have been considered but have not been found persuasive. Section 121 provides the Director of Patents and Trademarks with the authority to restrict applications to several claimed inventions when those inventions are found to be independent and distinct. In the instant application, the Examiner has determined that several independent and distinct inventions are claimed in the application. It is noted that Applicants have not argued that the various grouped inventions are not patentably distinct.

Further, different search considerations are involved for each of the different groups outlined in

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the Restriction Requirement. Although some of the groups have the same class, note that these groups have different subclasses. The Examiner has a very limited amount of time in which to examine each application. Therefore, it would impose a burden on the Examiner and the Patent Offices resources if the instant application were unrestricted. Additionally, the groups directed to method of use (i.e., Group XV) is a different filed of search as noted by its different classification from the compounds.

In accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is

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advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

The requirement is still deemed proper and is therefore made FINAL.

The scope of the elected invention that has been examined, inclusive of the elected species, is as follows:

X is NH;

Y is CO;

R₄ is indole;

R₂ is halogen; and

R₁ is HET¹.

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Subject matter not embraced by the above identified scope of the elected invention and claims 2-5, 7-26, 28-30 and 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply filed on April 18, 2005.

It is suggested that in order to advance prosecution, the non-elected subject matter be cancelled when responding to this Office Action.

Information Disclosure Statement

The Information Disclosure Statement filed on August 27, 2004 has been considered by the Examiner.

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Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the formula in instant claim 1 could not be found in the instant specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6, 27 and 31-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the

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specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The R_3 variable, found in the formula of claim 1, is not defined or described in the instant specification or in the originally filed claims. Therefore, the claims lack written description as such.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6, 27 and 31-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a) In claims 1 and 6, under the definition of Y, an "or" is needed after "CS".

b) In claims 1 and 6, defining R₂ as an "electron withdrawing group" is indefinite because the metes and bounds of the claims cannot be ascertained.

c) In claims 1 and 6, R₃, -HET¹ and -HET² are not defined in the claims.

d) In claims 1 and 6, it would appear that "Q₁" should be "Q¹".

e) In claim 1, the phrases "Each Q₁₅" and "Each Q₁₆" should be changed to "each Q₁₅" and "each Q₁₆", respectively.

f) In claim 6, under the definition of R₅, it is not possible to have a "C₁₋₄ alkenyl".

g) In claim 6, the phrases "Each Q₁₅" and "Each Q₁₆" should be changed to "each Q₁₅" and "each Q₁₆", respectively.

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h) In claim 6, under the definition of Q_{15} , the phrase "and $-SNQ_{16}Q_{16}$. The alkyl" should be changed to "and $-SNQ_{16}Q_{16}$; the alkyl".

i) In claim 6, under the definition of Q_{16} , the phrase "cycloalkyl. The alkyl" should be changed to "cycloalkyl; the alkyl".

j) In claim 6, $-HET^1$ and $-HET^2$ are not defined in the claim.

k) Claims 33-35 lack antecedent basis from claim 1 since there is no R_5 and R_6 stated in claim 1.

l) In claim 31, Q_{17} is not defined.

m) Claim 31 does not conform to M.P.E.P. 608.01(m) since each claim must end with a period and no other periods may be used elsewhere in the claims.

n) In claim 31, the phrase " $-CN$, $-NO_2$ $-OH$ " should be changed to " $-CN$, $-NO_2$, $-OH$ ".

o) In claim 31, under the definition of Z_n and Z_m , "halo, $-OH$, NO_2 " should be changed to "halo, $-OH$ or NO_2 " (last line of claim).

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- p) In claim 32, "formyl" lacks antecedent basis.
- q) In claim 32, an "or" is needed after "dimethylisoxazolyl".
- r) In claims 33 and 36, an "or" is needed before the last substituent listed.
- s) In claims 34 and 35, the "and" before the last substituent listed should be changed to "or".
- t) In claim 36, the third, fourth, sixth and tenth substituents listed lack antecedent basis.
- u) In claim 36, "tetrazol" is misspelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 6, 27 and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd et al. {U.S. Pat. 5,612,360} and Ushio et al. {WO 2002/12189}. Since the WO is in a non-English language, the U.S. equivalent, US 2003/0203909, will be referred to hereinafter.

*Determination of the scope and content of the prior art (MPEP
§2141.01)*

Applicants claim indole compounds. Boyd et al. (columns 2-4; and especially Example 22 in column 44) and Ushio et al. (page 2; and especially the compound in paragraph [0041] on page 3) each teach indole compounds that are structurally similar to the instant claimed compounds.

*Ascertainment of the difference between the prior art and the claims
(MPEP §2141.02)*

The difference between the compounds of the prior art and the compounds instantly claimed is that the

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instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating hypertension).

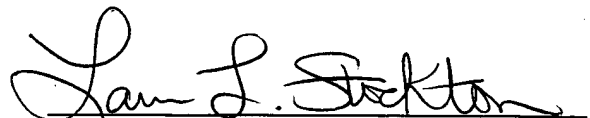
One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, hypertension. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

June 27, 2005